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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/655,336 09/05/00 UEDA

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| EXAMINER |
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HM12/1019

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| WANG, S | |
| ART UNIT | PAPER NUMBER |

1617
DATE MAILED:

9
10/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/655,336 | UEDA ET AL. | |
| | Examiner | Art Unit | |
| | Shengjun Wang | 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-18 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) 9, 10 and 12-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8, 11, 16-18, 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

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Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted July 31, 2001 is acknowledged.

1. Claims 9-10, 12-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.
2. The claims have been examined insofar as they read on the elected species.

Claim Rejections 35 U.S.C. 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 23-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 23 recites "... a composition *comprising isolated* theanine ...". It is confusing since the word "comprising" is inclusive, while the word "isolated" is exclusive. The claim is indefinite as to what components would be included in the composition and what would be excluded from the composition.
4. The term "crudely" in claim 24 is a relative term which renders the claim indefinite. The term "crudely" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The claim is indefinite as to the purity of the theanine.

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Claim Rejections 35 U.S.C. § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 8, 11, 16, 23 and 24 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by applicants' own admission for reasons set forth in the prior office action. Applicants' amendment, which limits the composition to those prepared by mixing theanine with other ingredients, is not seen to overcome the rejection particularly because tea is generally consumed in this country by mixing with other ingredient such as sugar, cream et al., in such a process, theanine is mixed with other ingredients. Claim 23 and 24 are properly rejected because tea is a theanine extract.

Claim Rejections 35 U.S.C. § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 8, 11, 16-18 and 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over applicants' admission in view of Wu et al. (CAPLUS Abstract, AN 1994:556550) and Yokoyama et al. (CAPLUS Abstract, AN:388386) for reasons essentially the same as stated in the prior office action. Regarding the new amendment, see the above discussion.

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3. Claims 8, 11, 16-18 and 21 –26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujii et al. (JPAB Pub-No. JP406100442A) in view of Brown et al. (Medline Abstract, AN 94068973), Dinning et al. (Medline Abstract, AN 92357882) and Woods et al. (Medline Abstract, AN 97401022) for reasons set forth in the prior office action, additionally, the simple step of mixing theanine with other ingredients in the composition to form the composition is seen to be obvious.

Response to the Arguments

4. Applicants' amendments and remarks submitted July 31, 2001 have been fully considered, but are not persuasive for reasons discussed below.

5. *Issue under 35 U.S.C. 102.* Applicants' assertion that the rejection is based on the fact that compositions containing theanine were known in the art is in error. The rejection is based on the fact that the process of administering composition containing theanine (tea) by PMS patient is in public use. The claims as amended is read on drinking tea as discussed above.

6. *Issue under 35 U.S.C. 103.* unpatentable over applicants' admission in view of Wu et al. (CAPLUS Abstract, AN 1994:556550) and Yokoyama et al. (CAPLUS Abstract, AN:388386). the amendments herein is not seen to over come the obvious rejection for reason discussed above. Regarding the remarks about references Wu and Yokoyama, note applicants have not rebutted examiner's statement that "tea composition is reasonably expected to comprise some mineral components."

7. *Issue under 35 U.S.C. 103* over Fujii et al. (JPAB Pub-No. JP406100442A) in view of Brown et al. (Medline Abstract, AN 94068973), Dinning et al. (Medline Abstract, AN 92357882) and Woods et al. (Medline Abstract, AN 97401022). Initially, applicants' argument is

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improper by bring materials not on the record. Further, In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, theanine is known to be useful for antistress (the primary reference) and stress is known to be closely related to PMS (secondary references), so it is prima facie obvious to use theanine for suppressing or ameliorating premenstrual syndrome.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Shengjun Wang

AU 1617

October 2, 2001

